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C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation

No. 2:15-MD-02641-DGC

DEFENDANTS C. R. BARD, INC. AND BARD PERIPHERAL VASCULAR, INC.'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO EXCLUDE OPINIONS OF ROBERT M. McMEEKING, PH.D.

(ASSIGNED TO THE HONORABLE DAVID G. CAMPBELL)

(Oral Argument Requested)

INTRODUCTION

Dr. McMeeking has failed to provide reliable opinions that will assist the trier-of-fact in this case with respect to four areas of his opinions. Therefore, Bard respectfully requests that the opinions identified below be excluded in this case.

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A. Dr. McMeeking's Opinion That Bard Did Not Go Far Enough to Reduce the Risks With its IVC Filters Is Not Based on an Appropriate Engineering Methodology and Is Therefore Unreliable.

Plaintiffs seek to have Dr. McMeeking opine first, that Bard retrievable filters are defective in various ways, and second, that Bard failed to practicably reduce risks in its filters. (Ex. A, McMeeking Dep. Tr., 23:9-18, July 6, 2017.) It is the second opinion that Bard seeks to exclude. Under a *Daubert* analysis, an expert must demonstrate that he has used scientific methodology appropriate in his area of expertise to support each opinion he seeks to provide. *Salinas v. Amteck of Ky., Inc.*, 682 F. Supp. 2d 1022, 1030 (N.D. Cal. 2010). Here, Dr. McMeeking has not done so. Dr. McMeeking presented certain work in this case through finite element analysis and calculations that he claims support his conclusions (i.e., that Bard retrievable filters have design defects and Bard could have altered the design of the devices to eliminate those alleged defects). That work, however, is not sufficient to support his opinion that Bard could have practicably reduced the risks in its filters yet failed to do so. In particular, he has failed to employ any methodology in determining, or make a detailed analysis of, the alternative design features he advocates. For example, he has made no analysis to show (1) that changes in the product that he claims could have been made would have reduced risks, (2) which risks such changes would have reduced, (3) the extent to which such changes would have reduced those risks, (4) whether such changes would have negatively impacted the retrievability of the filters, and (5) whether such changes would have otherwise caused unintended patient consequences.[1] Dr. McMeeking failed to conduct any engineering analysis beyond offering mere observations about what Bard could have done to modify its filters and made no effort to assess what outcomes those changes would have had with respect to the reduction of risks.

[1]Bard will show, through its engineering expert, other witnesses, and evidence that Dr. McMeeking's analysis of Bard's design and the conclusions he draws relative to purported design defects in Bard filters is a flawed and inaccurate analysis which does not support the conclusions Dr. McMeeking draws. Bard does not seek to exclude this portion of Dr. McMeeking's opinions.

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Dr. McMeeking's testimony makes clear that he has not performed the type of engineering analysis that could establish the reliability of this opinion. Instead of providing an engineering assessment of whether Bard could make changes to the product that would have reduced risks (while still maintaining the critical characteristic of retrievability), or providing an assessment of the extent to which Bard's modifications did reduce risks, Dr. McMeeking simply concludes summarily that Bard has failed to practicably reduce risks. In some instances, he dismisses Bard's filter modifications as having no effect on risks, while agreeing that he has done no analysis directly comparing the characteristics of the modified Bard filters to prior models. In other instances, he simply declines to provide any opinion as to whether those modifications in fact reduced risks in these filters, and if so, to what extent they did so, and as to which risks.

Dr. McMeeking's deposition is replete with testimony demonstrating that he has neither conducted an analysis nor employed any methodology to arrive at his conclusory opinion that Bard could have created alternative filter designs to reduce the risks associated with the devices:

> Q Okay. Is it your opinion that the various modifications that Bard has made along the way to its retrievable IVC filters did nothing to reduce the risks associated with either tilt, perforation, migration or fracture?
>
> THE WITNESS: The -- some of the changes that were made would have some effects on one or more of those phenomena that can take place in filters, and in some cases it's unclear whether the measure taken had the effect intended, but -- but there would have been some benefits from some of the changes which were made.

(Ex. A, McMeeking Dep. Tr., p. 25:11-23.)

> Q And you have not done work that would tell you what the specific modifications of filters that Bard has -- has included would do with respect to, for example, loads on the filter, strains that the filter is –

A I have not --

Q -- strains that the filter sees or loads that are put on those filters?

THE WITNESS: I have not done any calculations that specifically identify the detailed differences that would occur because of the design changes going from the G2X through to the Denali.

(*Id*. at 27:11 – 16; 27:24 – 28: 6.)

Q The other thing you talked about was that Bard could have redesigned the configuration of its filters. It was a little vague to me. What do you mean by that?

A Well, I mean the -- the shape of the limbs, the dimension of the limbs, in other words their -- their diameter, they could have considered different numbers of limbs, they could even have considered moving to a different material. So there's a fairly large number of design choices that could have been considered, and they could well have come up with a combination of features in the design that gave them a better combination of -- of phenomena in terms of how the filter behaved.

(*Id*. at 34:9 – 23.)

Q Have you done any work to determine what modifications Bard could have made to the legs themselves to improve on those legs' contribution, if any, to tilt, perforation, fracture or migration?

A No, I haven't looked into that.

Q We've talked a little bit about the anchors and limiters present on the Meridian. Is it your opinion that those are reasonable modifications by Bard to -- to improve resistance to migration, tilt and perforation?

A It's a reasonable concept for how the tilt and migration behavior can become -- can be limited.

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Q Would -- do you have an opinion whether those anchors or limiters on the Meridian would add fracture resistance to that filter?

A I have no opinion on that.

Q Same questions with Denali, do you think that the limiters that the Denali has will act to improve resistance to migration, tilt, perforation and fracture?

THE WITNESS: It's -- it is reasonable to expect that there will be some effect on -- on tilt and migration and that those would have possible knock-on consequences to perforation and fracture. And so I'd like to revise my answer about the Meridian in the same way, that the caudal anchors, to the extent they limit tilt and migration, they could have beneficial effects on perforation and fracture.

(*Id*. at 129:13 – 130:19.)

Q Do you have an opinion about whether any design modification that Bard made to the G2 filter resulted in caudal migration?

A I have no opinion on that because I have not studied it.

Q Okay. And have you done any work to determine how Bard might have modified its filters to reduce tilt that you associate with caudal migration, with contributing to caudal migration?

THE WITNESS: Well, the only observation I have is that the effective caudal anchors would have had a beneficial effect, but otherwise I've done no thinking or studying of that.

(*Id.* at 131:16 -18, 132:1 - 2; 132:18 – 133:1.)

Q Do you know of modifications to the Bard filters, any of them, that would have made them unable to fracture, tilt, perforate or migrate?

THE WITNESS: I haven't studied that.

(*Id*. at 149:18 – 21, 150:9.)

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> Q Having looked at the Denali filter, you do see that there are some differences in that filter than the previous ones, true?
>
> A Yes, that's correct.
>
> Q Okay. Is it your opinion that Bard has failed to reduce as far as reasonably practicable by taking adequate protection measures risks of tilt, perforation, fracture and migration in the Denali?
>
> A Yes.
>
> Q And what's the basis for that?
>
> A Because you still see incidences of all of those phenomena in Denali filters.

(*Id*. at 45:5 – 25.)

In short, Dr. McMeeking used no methodology and made no analysis in this litigation sufficient to opine that Bard failed to practicably reduce risks in its filters. *See Salinas*, 682 F. Supp. 2d at 1030. Therefore, Bard respectfully requests that his opinions in that regard be excluded here.

B. Dr. McMeeking's Opinion That Bard's Communications With the FDA Failed to Fully Communicate Relevant Information Regarding its IVC Filters Is Unreliable.

Dr. McMeeking has not been offered as an FDA regulatory expert in this litigation. While Plaintiffs state that Dr. McMeeking has appeared before the FDA previously, in some capacity (Pls. Resp. Br. (Doc. 7806), at 12, n. 9), Dr. McMeeking has not provided any regulatory analysis in this case, nor has he shown that he has the qualifications to interpret the appropriateness of Bard communications with the FDA or Bard's intent in providing those communications. In fact, he has testified that he relies on Dr. Parisian to provide such opinions in this litigation. (Ex. A, McMeeking Dep. Tr., 51:24 – 52:14, July 6, 2017.) In similar circumstances, courts have limited the scope of an expert's opinions where they venture into areas outside of their qualifications. *See e.g. Morritt v. Stryker Corp.*, 973 F. Supp. 2d 177, 188 (E.D.N.Y. 2013) (finding that a physician who had significant clinical experience with the medical device at issue went "well beyond the

'reasonable confines' of his clinical expertise" when offering opinions regarding biomedical engineering and material science); *In re: Breast Implant Litig.*, 11 F. Supp. 2d 1217, 1243-44 (D. Colo. 1998) (excluding design opinions of a scientist who held a Ph.D. in physical chemistry because being a chemist did not automatically qualify the witness on design issues when he lacked training and experience concerning design of breast implants).

While Dr. McMeeking has engineering expertise that may qualify him to provide opinions that certain Bard communications with the FDA contained technical inaccuracies, he cannot provide a reliable opinion in this case that Bard communications with the FDA were "misrepresentations" or a failure to be "frank and honest." Nor is he qualified to opine that Bard failed to inform the FDA appropriately regarding complications with its products. Those opinions, alone or as a whole, are not within the scope of Dr. McMeeking's expertise, and should be excluded as unreliable. *See e.g.*, *Morritt*, 973 F. Supp. 2d at 188*; Kruger v. Johnson & Johnson Professional, Inc.*, 160 F. Supp. 2d 1026, 1031 (S.D. Iowa 2001) (finding that a metallurgist was unqualified to offer design opinions regarding bone screws where he had no experience in the design of medical implants or any other medical devices); *In re: Breast Implant Litig.*, 11 F. Supp. 2d at 1243-44.

Furthermore, Dr. McMeeking does not provide an engineering methodology for how he ascertained that Bard's communications with the FDA were "misrepresentations," were not "frank and honest," or failed to provide the FDA with complication information. Rather, he relies on Dr. Parisian to support his opinions on the sufficiency and intent of Bard's communications with the FDA. (Ex. A, McMeeking Dep. Tr., 51:24 – 52:14, July 6, 2017.) In their Omnibus brief[2] (Pls. Omnibus Br. (Doc. 7799), at 7), Plaintiffs

[2] Plaintiffs filed a separate Omnibus Statement Of Law And Generally-Applicable Arguments In Opposition To Bard's Motions To Exclude Plaintiffs' Experts Under Rule 702 And Daubert (Doc. 7799). Plaintiffs' Omnibus Statement is not directed at any specific *Daubert* motion Bard filed. As such, Bard does not respond to the Omnibus Statement but instead will address any necessary issues in the context of its individual *Daubert* replies.

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concede it is impermissible for an expert to "merely act as a conduit for the other expert's opinion." *In re Toyota Motor Corp. Unintended Acceleration Mktg. Sales Practices, and Prods. Liab. Litig.*, 978 F. Supp. 2d 1053, 1066 (C.D. Cal. 2013) (emphasis added). As Plaintiffs further concede, the law requires the record to show that "the expert independently evaluated the evidence supporting the other expert's opinion." *Id.* In other words, there is no dispute that one expert cannot simply regurgitate the opinions of another and claim they support his own opinion, as Dr. McMeeking purports to do in this case.

Dr. McMeeking did not independently verify Dr. Parisian's work, did not analyze all of her source documents, and did not verify her methodologies. Instead, he simply assumed that her opinions are based on reliable methodologies and reliable underlying data. (Ex. A, McMeeking Dep. Tr., 51:24 – 52:14, July 6, 2017.) Because Dr. McMeeking uses Dr. Parisian's findings as a basis for his own opinion about the quality of Bard's FDA communications, without any independent verification of Dr. Parisian's work, Dr. McMeeking's opinion is unreliable, and should be excluded in this case.

C. Dr. McMeeking's Opinions on Filter Complication Rates Are Also Unreliable.

In his MDL deposition, Dr. McMeeking testified that he would not give opinions on filter complication rates in these cases (*Id*. at 175:14-176:1) and that he would not be giving opinions interpreting medical literature and incidence of complications. Despite that disclaimer, however, he insisted on opining that the medical literature reports of complications "tend to confirm that the filters are . . . dangerous." (*Id*. at 176:2-11.) Having agreed that he will not give opinions on rates, having performed no rate analysis of any kind, and having agreed that he has not interpreted medical literature, Dr. McMeeking has not provided the necessary methodology to allow him to give a reliable opinion that complications reported for Bard filters show that they are "dangerous." He should therefore be precluded from giving such an opinion in this case.

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In a related fashion, Dr. McMeeking also opines that the rates of complications in Bard retrievable filters, versus those in the Simon Nitinol Filter ("SNF"), support his conclusion that Bard filters are prone to complication. For that opinion, he again relies on the analysis of another one of the Plaintiffs' experts, this time Dr. Betensky. (Pls. Resp. Br., at 13:19-14:2.) As noted above, Plaintiffs concede that it is impermissible for an expert to "merely act as a conduit for the other expert's opinion" and that the law requires the record to show that "the expert independently evaluated the evidence supporting the other expert's opinion." (Pls. Omnibus Br., at 7.) Here, however, Dr. McMeeking admits he did not review any of the underlying adverse event data, let alone the Excel spreadsheets on which Dr. Betensky relied ("No, I did not look at her Excel sheets."). (Ex. A, McMeeking Dep. Tr., 186:4-12, July 6, 2017.) In fact, Dr. McMeeking did nothing to verify the reliability of Dr. Betensky's work ("Q. And you did not independently verify her work? A. No."). (*Id. at* 187:16-18.) Had he done so, Dr. McMeeking presumably would not have misrepresented Dr. Betensky's opinions as he has. Contrary to Dr. McMeeking's representations, Dr. Betensky never calculated "higher rates of fracture" for Bard retrievable filters over the SNF. (Ex. A to Bard's Motion to Exclude McMeeking, McMeeking 3/3/17 Rule 26 Report, at 25-26). In fact, Dr. Betensky never calculated any rates at all ("Q. You did not calculate any rate in connection with your expert opinions in this case, right? A. I did not calculate any rate. I calculated what I call risk or proportion."); ("Q. If someone described your report and stated that you had calculated any rates, that would not be a careful distinction between risk and rate, right? A. That would not be what I had done in my report."). (Ex. B, Betensky Dep. Tr., 139:24-140:2, 147:19-23, June 23, 2017.)

Rather than calculate a rate, as Dr. McMeeking mistakenly claims she did, Dr. Betensky instead calculated a "reporting risk ratio," ("RRR") which did nothing more than compare the proportions of anecdotal adverse event reports for the various retrievable filters over sales to the proportions of anecdotal adverse event reports for the SNF over SNF sales. Dr. Betensky emphasized that "the qualifier 'reported' is important and that's

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indicating that the data are coming from reports, and are not being derived from a beautifully run and designed experiment like a clinical trial, in which there's perfect follow-up and in which it's really a true experiment. So the 'reporting' qualifier is there to say and to suggest that these are numbers that are reported. These are based on reports." (Ex. C, Betensky Dep. Tr., 60:12-20, July 26, 2016.) Because of the inherent limitations in the data that she considered, Dr. Betensky described her RRR as a "crude estimate[] of risk." (*Id.* at 106:20-25.) Indeed, as she acknowledged, Dr. Betensky's RRR "could be an overestimate or it could be an underestimate" of risk. (*Id.* 62:14-19.) Hence, Dr. McMeeking's interpretation, without independent verification, that Dr. Betensky found that Bard retrievable filters have higher complication rates than the SNF is without scientific support and is, in fact, contrary to Dr. Betensky's own admissions. Given that Dr. McMeeking's reliance on Dr. Betensky's analysis is the basis for his opinion that Bard retrievable filter rates are high, or higher than the SNF, that opinion should be excluded in this case.

D. Dr. McMeeking's Opinion That SNF Is a Safer Alternative Product Is Unreliable and Should Be Excluded.

Dr. McMeeking's opinion that the SNF is a safer filter than Bard retrievable filters is neither reliable nor helpful. First, Plaintiffs and Dr. McMeeking ignore the fact that the SNF is a non-retrievable filter, making its function critically different from that of Bard's retrievable filters. While Bard filters were marketed as both permanent and retrievable filters, ignoring the retrievable function of these filters when arguing that the SNF is a safer alternative product is fatal to the reliability and helpfulness of Dr. McMeeking's opinions on this issue. As a product without the key feature of Bard's retrievable filters (retrievability), the SNF simply cannot be an alternative safer product. *See Clinton v. Brown & Williamson Holdings, Inc.*, 498 F. Supp. 2d 639, 645 (S.D.N.Y. 2007) (holding that the plaintiff's proffered alternative design must be the "functional equivalent" of the allegedly defective product); *Moss, by Gideon v. Wolohan Lumber Co.*, No. 92 C 7786, 1995 WL 348144, at *5 (N.D. Ill. June 7, 1995) (holding that proposed alternative design

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must exhibit same functions as allegedly defective product); *Mascarenas v. Cooper Tire & Rubber Co.*, 643 F. Supp. 2d 1363, 1369 (S.D. Ga. 2009) (proposed alternative design must be "equally efficacious"); *Casey v. Toyota Motor Eng'g & Mfg. N. Am., Inc.*, 770 F.3d 322, 331 (5th Cir. 2014) (proposed alternative design must not impair the product's utility). Indeed, while Dr. McMeeking compared certain SNF design documents to Recovery design documents, and made some observations and calculations about aspects of the SNF's design (including the SNF filter's stiffness) (Ex. A, McMeeking Dep. Tr., 193:6 – 195:22, July 6, 2017), he made no analysis of what changes would have to be made to an SNF filter to allow it to be retrieved:

> Q. Did you do any analysis of how one would make changes to either the petal dome or the legs of the SNF to allow it to be retrievable? . . .
>
> A. . . . But to move on to your subsequent question, I didn't make -- do any analysis to look at what changes might . . . impact they would have on the behavior of the filter . . .
>
> Q. How that might have to be re-engineered to allow for retrieval?
>
> A. I did not look at that.

(*Id.* at 205:16 – 17, 205:25 – 206:4, 206:8 – 10.) Therefore, Dr. McMeeking's opinion on this issue should be excluded here.

Plaintiffs dismiss Bard's argument that the SNF cannot be a safer alternative design, arguing that "Bard chose to rely on the SNF as the predicate device for its optionally retrievable filters, which requires those filters to be 'substantially equivalent' to the SNF. Bard then made the choice to have . . . the Recovery and G2, initially cleared for permanent use only – just like the SNF." (Pls. Resp. Br., at 17:19-18:5). In so arguing, Plaintiffs conflate the concepts of "substantial equivalence" under FDA regulations and the legal definition of an alternative safer design.[3] By doing so, Plaintiffs ignore the fact

[3] *In re Bair Hugger Forced Air Warming Devices Prod. Liab. Litig.*, No. MDL152666JNEFLN, 2017 WL 1373257, at *2 n.1 (D. Minn. Apr. 13, 2017) (acknowledging "[a]n FDA finding of substantial equivalence in the § 510(k) premarket approval process does not necessarily mean that the device under consideration has the same technological characteristics as the predicate device."); *In re Ethicon, Inc., Pelvic*

that though the Recovery and G2 are retrievable filters that can be placed permanently, the SNF is a permanent filter that *cannot* be retrieved percutaneously. Plaintiffs are essentially trying to argue that because the SNF was the predicate device for the Recovery and G2, the Recovery and G2 have the same design characteristics as the SNF. But that is false. They do not possess all of the same design characteristics.

The Plaintiffs also argue that the products considered in the safer alternative design cases to which Bard cites are distinguishable from Bard's retrievable filters here because those products functioned as intended. (*Id.* at 14-21). Plaintiffs' attempt to distinguish the *Felix*[4] and *McCarthy*[5] opinions from the instant case is unpersuasive. Both cases[6] stand for the proposition that "functional differences" between an allegedly defective product and the proffered alternative design are fatal to a plaintiff's case.[7] To avoid this result, Plaintiffs advocate for an overly narrow reading of the *Felix* and *McCarthy* holdings in an effort to limit the opinions' applicability only to cases where the alleged defect constitutes a functional aspect of the product. Plaintiffs' argument, however, ignores the reality exemplified by the case at hand that a product's allegedly defective design characteristics

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Repair Sys. Prod. Liab. Litig., No. 2:12-CV-4301, 2014 WL 505234, at *9 (S.D.W. Va. Feb. 5, 2014) (holding"[w]hile 510(k) approval may mean the ProteGen was "substantially similar" to the TVT, it did not mean the products were identical. A new device may be 'substantially equivalent' even though its technology is very different from the predicate device."); *Runnels v. Tahsin Indus. Corp., USA*, No. 3:11-CV-106-CWR-LRA, 2013 WL 6834632, at *12 (S.D. Miss. Dec. 23, 2013) ("A feasible design alternative is a design that would have to a reasonable probability prevented the harm without impairing the utility, usefulness, practicality or desirability of the product to users or consumers.").

[4] *Felix v. Akzo Nobel Coatings, Inc.*, 262 A.D.2d 447, 692 N.Y.S.2d 413 (2d Dept. 1999).

[5] *McCarthy v. Olin Corp.*, 119 F.3d 148 (2d Cir. 1997).

[6] Both *Felix* and *McCarthy* interpret the law of New York which has a more developed body of law on this issue compared to the relative dearth of case law in the bellwether jurisdictions. However, at least one court in the bellwether jurisdiction of Wisconsin has considered and ruled on this issue. *See Below v. Yokohama Tire Corp.*, No. 15-CV-529-WMC, 2017 WL 679153, at *4 (W.D. Wis. Feb. 21, 2017) (concluding that plaintiffs offered insufficient evidence that high-speed tire – proposed as an alternative design – was sufficiently similar to light truck tire – which was allegedly defective).

[7] *See Felix*, 262 A.D.2d at 448, 692 N.Y.S.2d 413 (rejecting proposed alternative design that was "not essentially the same" as the allegedly defective product because it exhibited "functional difference[s]"); *McCarthy*, 119 F.3d at 155 (rejecting proposed alternative design that lacked "functional element" present in allegedly defective product).

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may be integral to, but not necessarily constitute, the product's functionality. For example, in the case at hand, Plaintiffs have not alleged that retrievable filters are defective simply because they are retrievable. Rather, Plaintiffs argue that underlying design characteristics integral to the filters' retrievable function may constitute the alleged product defects. Nevertheless, under *Felix* and *McCarthy*, the non-retrievable SNF filter lacks the retrievable function of the Recovery and G2 filters, and this functional difference is fatal to Plaintiffs' use of the SNF filter as a proposed alternative design.

Dr. McMeeking's entire methodology supporting his opinion that the SNF is a safer alternative product -- including his calculations -- is based on the false premise that the non-retrievable SNF filter is functionally equivalent to the retrievable Recovery and G2 filters. However, Dr. McMeeking himself acknowledged the functional differences between the permanent SNF filter and the retrievable Recovery and G2 filters.[8] Because of these admitted functional differences, the permanent SNF filter is not a feasible alternative design for Bard's retrievable filters because it fails to match the additional utility of the retrievable filters. Dr. McMeeking's methodology and conclusions attempting to prove otherwise flout both the law and the facts.

Plaintiffs also argue that "If making Recovery, G2, and later filters retrievable also made them less safe in terms of tilt, perforation, migration, and fracture as compared to the SNF, then it was not appropriate for Bard to use the SNF as a predicate device." (*Id.* at 15, n. 15). Again, Plaintiffs misconstrue the definition of "substantial equivalence" and argue that alleged higher rates of complications in Bard retrievable filters make the SNF a safer alternative. The alleged higher rates in Bard retrievable filters compared to the SNF, on which Dr. McMeeking relies, come from an analysis by Plaintiffs' expert Dr. Betensky. Giving his interpretation of Dr. Betensky's analysis, Dr. McMeeking stated:

> I also have reviewed an analysis of adverse event reporting for the various Bard IVC filters [52]. This analysis was performed by . . . Dr. Rebecca Betensky, and was based on Bard's own

[8] Ex. B to Bard's Motion to Exclude McMeeking, McMeeking Dep. Tr., 221:16-223:3, July 6, 2017.

> internal adverse event data. Dr. Betensky's analysis [52] shows statistically significant differences between the Recovery and the Simon Nitinol Filter (SNF), the G2 and the SNF, the Eclipse and the SNF, the Meridian and the SNF, and the Denali and the SNF. Dr. Betensky's analysis [52] also shows that all Bard filters, including the Eclipse, Meridian, and Denali, had higher rates of fracture than SNF and that those higher rates of facture are statistically significant in comparison with SNF fracture rates . . . This adverse event analysis carried out by Dr. Betensky [52] is consistent with and supportive of my opinions in this report.

(Ex. A to Bard's Motion to Exclude McMeeking, McMeeking 3/3/17 Rule 26 Report, at 25-26.). In short, Dr. McMeeking has made it clear that his methodology regarding the comparison to the SNF is blind reliance on the opinions of Dr. Betensky. However, as previously noted, Dr. McMeeking's reliance on Dr. Betensky's work to support that opinion fails to provide the necessary methodology to make that opinion reliable.

As also discussed in Section C, *supra*, Dr. McMeeking's interpretation of the Betensky analysis is simply wrong. Rather than calculate a rate, Dr. Betensky calculated a "reporting risk ratio," ("RRR") which did nothing more than compare the proportions of anecdotal adverse event reports for the various retrievable filters over sales to the proportions of anecdotal adverse event reports for the SNF over SNF sales. Dr. Betensky described her RRR as a "crude estimate[] of risk," which "could be an overestimate or it could be an underestimate" of risk." (Ex. C, Betensky Dep. Tr., 62:14-19, 106:20-25, July 26, 2016.) Indeed, in her analysis, Dr. Betensky used data that was particularly flawed. Specifically, she used only sales and adverse event information for the SNF from the year 2000 forward, although she was aware that "the SNF was launched in 1990." (Ex. C to Bard's Motion to Exclude McMeeking, Betensky 1/27/17 Rule 26 Report, at 13.) She, therefore, omitted the first ten years of adverse event reports and sales data from her analysis of the SNF. (Ex. B, Betensky Dep. Tr., 125:20-126:2, June 23, 2017.) Because Dr. Betensky's reporting risk ratios might have increased for SNF with another ten years of adverse event data, her analysis is flawed. Simply put, Dr. Betensky has not established what the comparative rate of failures is through her analysis and Dr. McMeeking has done nothing to independently verify Dr. Betensky's results, let alone somehow transform her

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analysis into a true analysis of comparative rates. Consequently, Dr. McMeeking, in relying on Dr. Betensky's analysis, has used improper methodology to conclude that SNF complication rates are lower than those with Bard retrievable filters -- the critical underlying assumption for his opinion that the SNF is a safer filter than Bard retrievable filters.

As demonstrated above, even if the SNF could be compared to Bard retrievable filters for relative safety, which Bard shows it cannot be, the Betensky analysis used by Dr. McMeeking to reach his conclusion that the SNF is a safer filter is unreliable and therefore makes his opinion unreliable (and inadmissible). Therefore, Dr. McMeeking's opinions that the SNF is a safer filter should be excluded in this case.

CONCLUSION

Dr. McMeeking's analyses and methodology are insufficient, and/or rely on opinions and analyses of other experts without verifying those opinions. Therefore, the opinions discussed in this motion are unreliable and/or will not help the trier-of fact to determine the issues presented in this case. As a result, Bard respectfully requests that the Court exclude those opinions here.

DATED this 18th day of October, 2017.

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CERTIFICATE OF SERVICE

I hereby certify that October 18th 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

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